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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/011,659	11/29/2001	Eric R. George	ZE-46	6878

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EXAMINER	
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ART UNIT	PAPER NUMBER
1772	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/011,659	GEORGE ET AL.	
	Examiner	Art Unit	
	Walter B Aughenbaugh	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2004 and 01 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *86-108* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *86-108* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 21, 2004 has been entered.

Acknowledgement of Applicant's Amendments

2. New claims 86-108 presented in the Amendment filed July 21, 2004 (Amdt. B) have been received and considered by Examiner.

3. The cancellation of claims 67-85 in Amdt. B has been acknowledged by Examiner.

WITHDRAWN OBJECTIONS AND REJECTIONS

4. All objections and rejections made of record in the previous Office Action mailed March 29, 2004 have been withdrawn due to the cancellation of claims 67-85 in Amdt. B.

NEW OBJECTIONS

Specification

5. The amendment filed July 21, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The 1-10% range claimed in claims 90, 97 and 98 is not supported in the specification. N.B. page 30, line 21 of the specification establishes a range of 2-10%.

Applicant is required to cancel the new matter in the reply to this Office Action.

NEW REJECTIONS

Claim Rejections - 35 USC § 112

6. Claims 90, 97 and 98 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The 1-10% range is not supported in the specification. N.B. page 30, line 21 of the specification establishes a range of 2-10%.

7. Claims 99-102 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In regard to claims 99 and 100, an elongation to break of what? In regard to claims 101 and 102, the product of the elongation to break and the tensile strength of what?

Claim Rejections - 35 USC § 103

8. Claims 86-92 and 95-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bagaoisan et al. in view of Beall et al.

In regard to claim 86, Bagaoisan et al. teach tubing formed from a polymer blend (a blend of nylon and Pebax (TM) copolymer) where the blend comprises a first regular polymer chain (nylon) comprising the reaction products of at least a first monomer and a second polymer comprising block chain segments (Pebax (TM)) consisting essentially of the at least a first monomer (nylon) and block chain segments of a second monomer (ether) (col. 9, lines 12-16;

Pebax (TM) designates a group of nylon/polyether copolymers as evidenced by Applicant's specification on page 19, lines 25-26). Bagaoisan et al. teach that different materials are also combined with the blend or blended in the blend to select for desirable flexibility properties (col. 9, lines 12-20).

Bagaoisan et al. fail to explicitly teach that the different (i.e. additional) material to be combined with the blend or blended in the blend to select for desirable flexibility properties is nanoparticles.

Beall et al., however, disclose a matrix polymer/platelet nanocomposite (col. 1, lines 65-66) material for use where it is desired to alter one or more physical properties of a matrix polymer, such as elasticity characteristics (col. 1, lines 33-43). Beall et al. disclose that nanoscale platelet particles of high strength and modulus dispersed throughout a polymer matrix imparts greater mechanical reinforcement to the polymer matrix than do comparable loadings of conventional reinforcing fillers of micron-scale size (col. 6, lines 32-39). Beall et al. disclose that nylons are useful as the matrix polymer (col. 17, line 57-col. 18, line 40). Therefore, one of ordinary skill in the art would have recognized to have blended the nanoscale platelet particles of Beall et al. with the nylon polymer blend of Bagaoisan et al. in order to impart superior mechanical reinforcement to the nylon polymer blend of Bagaoisan et al. as taught by Beall et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have blended the nanoscale platelet particles of Beall et al. with the nylon polymer blend of Bagaoisan et al. in order to impart superior mechanical reinforcement to the nylon polymer blend of Bagaoisan et al. as taught by Beall et al.

In regard to claim 87, Bagaoisan et al. teach tubing formed from a polymer blend (a blend of nylon and Pebax (TM) copolymer) where the blend comprises a first homopolymer formed from one or more monomers to provide a regular linear chain of polyamide segments (nylon) and a second polymer comprising one or more polyamide block segments formed form the one or more monomers and one or more flexible polyether block segments (col. 9, lines 12-16; Pebax (TM) designates a group of nylon/polyether copolymers as evidenced by Applicant's specification on page 19, lines 25-26). Bagaoisan et al. teach that different materials are also combined with the blend or blended in the blend to select for desirable flexibility properties (col. 9, lines 12-20).

Bagaoisan et al. fail to explicitly teach that the different (i.e. additional) material to be combined with the blend or blended in the blend to select for desirable flexibility properties is nanoparticles.

Beall et al., however, disclose a matrix polymer/platelet nanocomposite (col. 1, lines 65-66) material for use where it is desired to alter one or more physical properties of a matrix polymer, such as elasticity characteristics (col. 1, lines 33-43). Beall et al. disclose that nanoscale platelet particles of high strength and modulus dispersed throughout a polymer matrix imparts greater mechanical reinforcement to the polymer matrix than do comparable loadings of conventional reinforcing fillers of micron-scale size (col. 6, lines 32-39). Beall et al. disclose that nylons are useful as the matrix polymer (col. 17, line 57-col. 18, line 40). Therefore, one of ordinary skill in the art would have recognized to have blended the nanoscale platelet particles of Beall et al. with the nylon polymer blend of Bagaoisan et al. in order to impart superior mechanical reinforcement to the nylon polymer blend of Bagaoisan et al. as taught by Beall et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have blended the nanoscale platelet particles of Beall et al. with the nylon polymer blend of Bagaoisan et al. in order to impart superior mechanical reinforcement to the nylon polymer blend of Bagaoisan et al. as taught by Beall et al.

In regard to claims 88, 89, 91 and 92, Bagaoisan et al. teach tubing formed from a polymer blend (a blend of nylon and Pebax (TM) copolymer) where the blend comprises a first condensation polymer consisting essentially of a first monomer having a first pair of reactive end groups (nylon) and a second polymer comprising block segments of a second monomer having the first pair of reactive end groups and block segments of a third monomer (col. 9, lines 12-16; Pebax (TM) designates a group of nylon/polyether copolymers as evidenced by Applicant's specification on page 19, lines 25-26). Bagaoisan et al. teach that different materials are also combined with the blend or blended in the blend to select for desirable flexibility properties (col. 9, lines 12-20).

Bagaoisan et al. fail to explicitly teach that the different (i.e. additional) material to be combined with the blend or blended in the blend to select for desirable flexibility properties is nanoparticles.

Beall et al., however, disclose a matrix polymer/platelet nanocomposite (col. 1, lines 65-66) material for use where it is desired to alter one or more physical properties of a matrix polymer, such as elasticity characteristics (col. 1, lines 33-43). Beall et al. disclose that nanoscale platelet particles of high strength and modulus dispersed throughout a polymer matrix imparts greater mechanical reinforcement to the polymer matrix than do comparable loadings of conventional reinforcing fillers of micron-scale size (col. 6, lines 32-39). Beall et al. disclose that

nylons are useful as the matrix polymer (col. 17, line 57-col. 18, line 40). Therefore, one of ordinary skill in the art would have recognized to have blended the nanoscale platelet particles of Beall et al. with the nylon polymer blend of Bagaoisan et al. in order to impart superior mechanical reinforcement to the nylon polymer blend of Bagaoisan et al. as taught by Beall et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have blended the nanoscale platelet particles of Beall et al. with the nylon polymer blend of Bagaoisan et al. in order to impart superior mechanical reinforcement to the nylon polymer blend of Bagaoisan et al. as taught by Beall et al.

In regard to claims 95 and 96, Beall et al. disclose that nylon 6 and nylon 12 are suitable materials for the nylon of the nanocomposite material (col. 18, lines 28-37).

In regard to claims 90, 97 and 98, Beall et al. disclose that the most preferable amount of nanoscale platelet particles to be dispersed in the matrix polymer is 0.05% to about 20% or 0.05% to about 10% by weight of the composite (col. 15, lines 20-27). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have blended the nanoscale platelet particles of Beall et al. with the nylon polymer blend of Bagaoisan et al. in an amount of 0.05% to about 20% or 0.05% to about 10% by weight of the composite in order to impart superior mechanical reinforcement to the nylon polymer blend of Bagaoisan et al. as taught by Beall et al.

In regard to claims 99-102, Bagaoisan et al. teach that the tubing has an internal diameter of about 0.10 inches (col. 5, lines 26-40 and col. 3, lines 59-64), an internal diameter that falls within the claimed range of about 0.001 to about 0.5 inches. The blend of Bagaoisan et al. necessarily has an elastic modulus between the modulus of the first polymer with the same

weight % of nanoparticles as the polymer blend and the modulus of the second polymer by virtue of the fact that it is a blend. Beall et al. disclose that the most preferable amount of nanoscale platelet particles to be dispersed in the matrix polymer is 0.05% to about 20% or 0.05% to about 10% by weight of the composite (col. 15, lines 20-27). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have blended the nanoscale platelet particles of Beall et al. with the nylon polymer blend of Bagaoisan et al. in an amount of 0.05% to about 20% or 0.05% to about 10% by weight of the composite in order to impart superior mechanical reinforcement to the nylon polymer blend of Bagaoisan et al. as taught by Beall et al.

Claims 103-105 consist entirely of method limitations that have not been given patentable weight since the method of forming the tubing is not germane to the issue of the patentability of the tubing itself.

In regard to claims 106-108, Bagaoisan et al. teach that the tubing has an internal diameter of about 0.10 inches (col. 5, lines 26-40 and col. 3, lines 59-64), an internal diameter that falls within the claimed range of about 0.001 to about 0.5 inches.

9. Claims 93 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bagaoisan et al. in view of Beall et al. and in further view of Wang et al.

Bagaoisan et al. and Beall et al. teach the tubing as discussed above in regard to claim 88. Beall et al. disclose that polyester is a suitable matrix polymer for the nanoparticles (col. 18, lines 41-67). Bagaoisan et al. and Beall et al. fail to explicitly teach that the first condensation polymer is a crystallizable polyester as claimed in claim 93 and that the third monomer forms a polyether as claimed in claim 94. Wang et al. teach that blends of at least two of polyesters,

polyamides, polyether-polyester copolymers and polyether-polyamide copolymers are notoriously well known polymeric blends used to form catheter balloons (col. 2, lines 25-35). Therefore, one of ordinary skill in the art would have recognized to have replaced the blend of polyamide and polyether-polyamide copolymer taught by Bagaoisan et al. with the blend of polyester and polyether-polyester copolymer taught by Wang et al. since both blends are notoriously well known polymeric blends used to form catheter balloons as taught by Wang et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have replaced the blend of polyamide and polyether-polyamide copolymer taught by Bagaoisan et al. with the blend of polyester and polyether-polyester copolymer taught by Wang et al. since both blends are notoriously well known polymeric blends used to form catheter balloons as taught by Wang et al.

Response to Applicant's Arguments

10. Applicant's arguments on pages 2-8 of the Amdt. B regarding the proposed combination of Bagaoisan et al. and Beall et al. have been fully considered but are not persuasive.

Since Bagaoisan et al. teaches that "[d]ifferent materials might also be combined or blended to select for desirable flexibility properties" (col. 9, lines 18-19) one of ordinary skill in the art would have motivated by this teaching to consult Beall et al. for a teaching of a material that would increase the stiffness of the blend of Bagaoisan et al. (i.e. nanoparticles). Applicant argues on page 4 of Amdt. B that this teaching of Bagaoisan et al. "would motivate one to add a filler to [only] a single polymer", but this is not true because Bagaoisan et al. plainly teaches a blend of nylon and Pebax (TM) (col. 9, line 16), so one of ordinary skill in the art would have recognized to have blended the nanoparticles of Beall et al. in with the blend of nylon and Pebax

(TM) of Bagaoisan et al. in order to increase the stiffness of the blend where desired. The amount of filler that would be required and any complexity to blend the components is irrelevant to the patentabilty of the tubing formed from the blend.

In the second full paragraph of page 5 of Amdt. B, Applicant seems to argue that the teaching of the blend of nylon and Pebax (TM) at col. 9, line 16 of Bagaoisan et al. applies only to the tip of the catheter, but the paragraph at col. 9, lines 12-19 applies only to the tubular body, item 16; the paragraph at col. 9, lines 12-19 teaches that the tubular body, item 16, is formed of a blend of nylon and Pebax (TM), not that the tip is formed of a blend of nylon and Pebax (TM).

The excerpt from *Principles of Polymer Science* (Rodriguez) does not establish that hardness is equivalent to modulus. The statement that "Since the measurement is basically a compressive modulus, one expects stiff materials to be hard and flexible materials to be soft" from Rodriguez is not an absolute statement that equates hardness and modulus, but rather sets forth a general trend which may or may not be true in the instance of the particular material claimed by Applicant.

In regard to Applicant's argument on page 5 of Amdt. B (and again on page 6) that it must be shown "that the prior art teaches that the compositions and proportion ranges are known to produce all of the utilitarian properties discovered by the Applicant and described in the disclosure", the result effective variable need not be any particular result effective variable/s Applicant had in mind while developing the claimed subject matter.

Applicant argues that Applicant has shown unexpected results in their specification in that the mechanical properties obtained from blending the two polymeric components would not be expected based on knowledge of how the mechanical properties of individual components to

be blended translate to the mechanical properties of the blend, but the issue in this particular case, as required by the nature of the rejection, is not whether blending two polymers together would lead to unexpected results (as Applicant relies upon for the basis of their argument in Amdt. B and in the 132 Declaration), but whether adding the nanoparticles of Beall et al. to the blend taught by Bagaoisan et al. would lead to unexpected results. It is Examiner's position that an increase in the modulus of elasticity of the blend taught by Bagaoisan et al. as a result of adding the nanoparticles of Beall et al. to the blend taught by Bagaoisan et al. would not be unexpected since Beall et al. disclose that nanoscale platelet particles of high strength and modulus dispersed throughout a polymer matrix imparts greater mechanical reinforcement to the polymer matrix than do comparable loadings of conventional reinforcing fillers of micron-scale size (col. 6, lines 32-39).

RESPONSE TO DECLARATION UNDER 37 CFR 1.132

11. It is stated in paragraph 12 of the Declaration that the main point of Bagaoisan et al. is to use a softer polymer in the tip of the catheter to lower the modulus of elasticity of the tip; regardless of whether or not this is the main point of Bagaoisan et al., the paragraph at col. 9, lines 12-19 teaches that the tubular body, item 16, is formed of a blend of nylon and Pebax (TM), not that the tip is formed of a blend of nylon and Pebax (TM).

It is stated in paragraph 13 of the Declaration that the "[d]ifferent materials might also be combined or blended to select for desirable flexibility properties" statement of Bagaoisan et al. (col. 9, lines 18-19) only motivates one to use a blend at the tip, but the paragraph at col. 9, lines 12-19 applies only to the tubular body, item 16; the paragraph at col. 9, lines 12-19 teaches that the tubular body, item 16, is formed of a blend of nylon and Pebax (TM), not that the tip is

formed of a blend of nylon and Pebax (TM). "Motivation" to form a blend is not even an issue here, Bagaoisan et al. explicitly teaches that the tube, not the tip, is made of a blend in the paragraph at col. 9, lines 12-19.

In regard to paragraph 17 of the Declaration, Exhibits 4-6 are not included in the IFW file. Regardless, Applicant argues that Applicant has shown unexpected results in their specification in that the mechanical properties obtained from blending the two polymeric components would not be expected based on knowledge of how the mechanical properties of individual components to be blended translate to the mechanical properties of the blend, but the issue in this particular case, as required by the nature of the rejection, is not whether blending two polymers together would lead to unexpected results, but whether adding the nanoparticles of Beall et al. to the blend taught by Bagaoisan et al. would lead to unexpected results. It is Examiner's position that an increase in the modulus of elasticity of the blend taught by Bagaoisan et al. as a result of adding the nanoparticles of Beall et al. to the blend taught by Bagaoisan et al. would not be unexpected since Beall et al. disclose that nanoscale platelet particles of high strength and modulus dispersed throughout a polymer matrix imparts greater mechanical reinforcement to the polymer matrix than do comparable loadings of conventional reinforcing fillers of micron-scale size (col. 6, lines 32-39).

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is 571-272-1488. The examiner can normally be reached on Monday-Thursday from 9:00am to 6:00pm and on alternate Fridays from 9:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Walter B. Aughenbaugh
01/10/05

WBA

1772

1/10/05